State of Alaska

Department of Commerce, Community & Economic Development Division of Corporations, Business & Professional Licensing

BOARD OF PHARMACY MINUTES OF THE TELECONFERENCE Friday March 4th, 2016

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled teleconference of the Board of Pharmacy was held at the State Office Building, 333 Willoughby Avenue, Friday March 4th, 2016 beginning at 2:00 p.m. The meeting was held in Conference Room A, 9th Floor Juneau, Alaska.

Agenda Item 1 <u>Call to Order/Roll Call</u>

The meeting was called to order by Chair, John Cotter at 2:05 pm

Board Members Present, constituting a quorum:

John Cotter, RPh Leif Holm, PharmD Bill Altland, RPh Phil Sanders, RPh Anne Gruening, Public Member

Attending from the Division of Corporations, Business and Professional Licensing were:

Donna Bellino, Licensing Examiner
Mary Sikes, Licensing Examiner
Janey Hovenden, Division Director
Sara Chambers, Division Operations Manager

Invited to attend for historical knowledge of Board of Pharmacy Bills and CSA White Paper:

CJ Kim, RPh – Former Board of Pharmacy Member

Agenda Item 2 Review Agenda

The Board reviewed the agenda for the March 4th, 2015 Meeting.

On a motion duly made by John Cotter, seconded by Bill Altland, and approved unanimously, it was

RESOLVED to accept the agenda as written.

Agenda Item 3 <u>Ethics</u>

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The Board had no ethics disclosures.

Agenda Item 4 Pharmacy Legislative Bill Review & Discussion

Chair, John Cotter introduced new board member Phil Sanders. Mr. Sanders just became a member of the Board of Pharmacy on March 1, 2016.

Sara Chambers addressed the Board and provided a general overview and update to the board on where things are currently at with the legislative bills that impact the pharmacy board. There has been a "brush fire" of pharmacy related bills that have been filed all at once which is exciting and challenging at the same time. There have been a few changes and the SB Work Draft for PDMP legislation is off the table. SB166, HB344, and SB74 are currently being heard in one committee or another and all three bills impact the PDMP. SB74 seems to be getting the most traction and it has quite a bit of fire power behind it. It is the Medicaid reform bill that the legislature met on in special session last year. It continued to be Medicaid reform then all of a sudden it was PDMP, and now just added yesterday was telemedicine. SB74 has become quite a big Bill for the Division and probably the Bill that will be the leading PMDP vehicle.

SB166 has not gotten a lot of activity, and HB344 was just heard for the first time earlier this week and is scheduled to be heard next week. HB344 is the house version of the Bill and is trying to be the most responsive to recommendations that came out of the Controlled Substance Advisory Committee, but it is very different than SB74. These are the three PDMP bills, but only two of the three Bills seem to be moving HB344 and SB74.

There are two other Bills HB297 and SB201 that the Board requested that is seeking statutory authority to license out-of-state wholesale drug distributors has not been called to a hearing yet. Ms. Chambers understands these two Bills are ones that Board has backed in concept for the last few years and has worked with legislators on. Ms. Chambers stated she would like to hear the Board's views on the PDMP bills and perhaps a vote on the Boards position on the PDMP Bills.

HB169 Contraceptive Prescription and SB175 Pharmacy Benefits Managers are more of a heads up to the Board and don't necessarily have a big impact from the Division or licensing function, but are pharmacy related. Ms. Chambers did advise the Board to let her know if these two Bills cross over and impact pharmacy statutes or have a licensing impact.

The main reason for the teleconference is to get the Board's official statement and share any concerns, amendments or changes they may have on all of the pharmacy related Bills.

Ms. Chambers reviewed the draft of the Fiscal Note submitted for SB74. The Division's Fiscal Note requests \$560,000 of authority, not general fund money. This is the expenditure authority for the first year and goes up to \$607,000 in the out years. Ms. Chambers provided the details for those numbers.

\$443,600 is requested for Personal Services expenses for one full-time Program Coordinator 1. This position would manage the PDMP program and potentially supervise the Licensing Examiner. The next

four positions would be needed due to the changes in the telemedicine bill: Two full-time Licensing Examiners and two full-time Investigator III positions. The only position that would be geared toward pharmacy would be the Program Coordinator. The Division took the opportunity to put in the Program Coordinator position not only because of the expansion of the PDMP and state's augmentation of the opioid control program, but we are at point to have a full-time person manage the program. The Board has previously spoken about having this type of position and included in HB297/SB201 the authority to have and Executive Administrator for the Board of Pharmacy.

The remaining costs include \$3,000 per year in travel for the Program Coordinator, \$12,000 for printing and postage. \$2,000 for contract with PDMP vendor to expand database program from monthly to weekly and \$108,000 for legal costs of investigators and appeals beginning in year two, and lastly \$50,000 for department wide services to support the new positions.

SB74 itself has quite a few changes and some of the changes are present in SB166 and HB344 and some are not. The biggest change in SB74 is the inclusion of the recommendations from the Controlled Substance Advisory Committee. SB74 is the Bill that comes the closest vehicle to adopting those, and what the CSAC has recommended is most fully realized in SB74.

The Board reviewed the changes to the Bill and the classification of controlled substances to be reported is Class II, Class III, and Class IV. Federal Class V was removed from reporting. Per the outcome of the Board's discussion on Class V drugs, the Board would like to make the following recommendation that a Schedule Class V drug that requires a prescription be preceded by a prescription and request that this be added into the legislation.

On a motion duly made by John Cotter, approved unanimously, it was

RESOLVED to have scheduled Class V drugs that require a prescription be preceded by a prescription and request this be added into the legislation.

The Board reviewed changes in HB344 who would have access to the PDMP and voted on the following:

On a motion duly made by John Cotter, seconded by Anne Gruening and approved unanimously,

RESOLVED to leave Agent or Employee as written in SB74.

The Board reviewed the changes in HB344 #7 allowing Medicaid to have access to the PDMP and voted by a roll call vote on whether or not to allow Medicaid access to the PDMP:

On a motion duly made by John Cotter and voted on by roll call

RESOLVED, to allow Medicaid to have access to the PDMP

Motion failed to allow Medicaid access to the PDMP.

John Cotter - No, Phil Sanders - No, Leif Holm - No, Bill Altland - Yes, Anne Gruening - Passed on the vote

The Board reviewed the changes in HB344 #8 utilization review of prescription drugs for the medical assistance program under AS 47.07 and voted by a roll call vote to allow or deny access to the PDMP:

On a motion duly made by John Cotter and voted on by roll call

RESOLVED to allow utilization review of prescription drugs for the Medicaid assistance program.

John Cotter – No, Bill Altland – pass, Phil Sanders – No, Leif Holm – No, Anne Gruening – No

The Board reviewed changes in HB344 #9 State Medical Examiner to the extent that the information relates specifically to investigating the cause and manner of a person's death.

On a motion duly made by John Cotter and approved unanimously, it was

RESOLVED, to allow state medical examiner access as stated in #9.

The Board reviewed and discussed HB344 #10 an authorized employee of the Department of Health and Social Services may receive information from the database that does not identify patients, prescribers, dispensers, or dispenser locations, for the purpose of identifying and monitoring public health issues in the state.

On a motion duly made by John Cotter and approved unanimously, it was

RESOLVED to agree that an authorized employee of the Department of Health and Social Services may receive information from the PDMP database.

Ms. Chambers addressed Chair, John Cotter and asked because there are three Bills that have a lot of similarities, is the Board's vote on the above apply to any of the three Bills where these items are substantially similar and not just HB344. Mr. Cotter and the Board agreed the votes go across all three Bills that have the same or similar wording in them.

The Board reviewed and discussed HB344 (A) access the database to check a patient's prescription records before dispensing a controlled substance to the patient.

On a motion duly made by John Cotter and approved unanimously, it was

RESOLVED to have HB344 (A) be removed from the Bill.

The Board reviewed and discussed HB344 (B) enter a prescription into the database at near real time to when a controlled substance is dispensed under (b) of this section.

On a motion duly made by John Cotter and approved unanimously, it was

RESOLVED to change near real time to a week or less.

The Board then reviewed HB44 (p) that the Board shall develop in the database an alert system that automatically sends an electronic notification to a pharmacist and practitioner at the time the pharmacist or practitioner enters a prescription for a patient into the database if the same patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance.

The Board is in support of the concept of this, but would like to have more details on how the PDMP vendor can generate such an alert. Ms. Chambers will speak with Brian Howes to find out more information regarding this.

Mr. Cotter then commented on HB297 "An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy.

Mr. Cotter made a comment on the record that he believes HB297 is an extremely important Bill for the Board of Pharmacy. Not only would the passage of HB297 bring Alaska into compliance with the FDA's DQSA(Drug Quality Supply Chain Act) that became law in November 2013, but would allow for the Board to hire an Executive Administrator for the Board to assist with the increase of regulatory issues since DQSA became law.

Ms. Chambers advised the Board that there is not an "official" statement from the Board on HB297. The Board will draft a letter of support for the Bill and will send one to both the House and Senate. Ms. Bellino will work with Anne Gruening, Secretary for the BOP on composing the letter.

3:25 pm Ms. Chambers advised the Board that she had a meeting she could not miss and left the meeting.

The Board of Pharmacy went on the record in support of SB23 - An Act relating to the practice of pharmacy; relating to the dispensing of opioid overdose drugs by a pharmacist.

The Board reviewed/discussed on the record the "White Paper" that was the result of the Controlled Substance Advisory Committee. The "White Paper" was sent to Governor Walker and contained nine recommendations for modifications to Alaska's PDMP:

The CSAC recommended the following:

- Require all prescribers and all pharmacists to register with the Alaska PDMP.
- 2) Require prescribers and pharmacists to review the PDMP database when prescribing or dispensing a controlled substance to a patient.
- 3) Authorize prescribers and pharmacists to delegate database access to supervised employees or clinical staff.

- 4) Authorize the Board of Pharmacy to forward unsolicited notifications to prescribers and dispensers database information about patients who may be obtaining controlled substances inconsistent with generally recognized standards of care.
- 5) Collect dispensing data and updating the PDMP database weekly.
- 6) Authorize PDMP database access to the State of Alaska Medicaid Pharmacy Program.
- 7) Authorize PDMP database access to the Alaska Medicaid Drug Utilization Review Committee.
- 8) Authorize PDMP database access to the State of Alaska Medical Examiner.
- 9) Authorize de-identified PDMP data access to the State of Alaska Department of Health and Social Services (Alaska DHSS) Division of Public Health.

The Board of Pharmacy is in support of the nine CSAC recommendations, but has some concerns with #2, #6, & #7. The Board's earlier votes reflect those concerns.

The Board went on record in support of SB169 – An Act relating to the authority of pharmacists to prescribe and dispense self-administered hormonal contraceptives.

The Board concluded the teleconference.

On a motion duly made by John Cotter, seconded by Anne Gruening, and approved unanimously, it was $\frac{1}{2} \int_{\mathbb{R}^{n}} \frac{1}{2} \int_{\mathbb{$

RESOLVED to adjourn the teleconference meeting.

Off the record at 4:05 pm

Respectfully Submitted:

Donna Bellino

Licensing Examiner

Approved:

John Cotter, RPh., Chair

Date: 5-4-16